EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

29 June 2018

Application to intervene

(Interest in the result of the case – Accredited Stakeholder Organisations)

Case number	A-001-2018
Language of the case	English
Appellant	BrüggemannChemical, L. Brüggemann GmbH & Co. KG, Germany
Representative	Martin Ahlhaus Noerr LLP, Germany
Contested Decision	CCH-D-2114373456-42-01/F of 10 November 2017 adopted by the European Chemicals Agency pursuant to Article 41(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')
Applicant	The European Coalition to End Animal Experiments, United Kingdom

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 12 February 2018, the Appellant filed an appeal against a decision following a compliance check of the Appellant's registration for the substance sodium hydroxymethanesulphinate (EC No 205–739–4, CAS No 149-44-0; the 'Substance').

2. The Contested Decision requires the Appellant to submit information on a carcinogenicity study, a pre-natal developmental toxicity ('PNDT') study and an extended one-generation reproductive toxicity study ('EOGRTS') in accordance with Sections 8.9.1, 8.7.2 and 8.7.3 of Annex X to the REACH Regulation respectively.

3. On 19 April 2018, an announcement of the appeal was published on the Agency's website in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').

4. On 9 May 2018, the European Coalition to End Animal Experiments ('ECEAE') applied for leave to intervene in the proceedings in support of the Appellant.

5. On 15 May 2018, the Appellant stated that it had no objections to ECEAE's application for leave to intervene.

6. On 29 May 2018, the Agency requested the Board of Appeal to dismiss the application.

Arguments

Arguments of the Applicant

7. ECEAE states that it is Europe's leading alliance of animal protection organisations, representing many millions of people in the European Union who are concerned about animal testing. It claims to have an interest in the result of the case because it has been an accredited stakeholder of the Agency from the outset and has worked with the Agency to improve its guidance to industry, in particular on the avoidance of animal testing.

8. ECEAE argues that it has long been concerned about the implications for animal welfare of the Agency's approach to the decision-making process, and how the Agency exercises its discretion. In the present case, ECEAE has a particular interest in the Agency's refusal to take into account information submitted after the Agency's self-imposed cut-off point in the decision-making process after which new information will not be considered as this may have had an impact on the request for animal testing, especially the carcinogenicity study.

9. ECEAE argues that, because of the Agency's rigid adherence to timescales and the cut-off point after which new information will not be considered by the Agency, studies may be required for which there is no scientific justification and in breach of Article 25 of the REACH Regulation which requires testing on vertebrate animals to be undertaken only as a last resort.

10. ECEAE argues that a large number of animals would suffer unnecessarily if the studies requested in the Contested Decision are performed. ECEAE argues that it and its members have an obvious interest in ensuring that animal suffering on the scale implied by the three requested studies (see paragraph 2 above) does not take place if it is not warranted.

Arguments of the Agency

11. The Agency objects to the application on the grounds that, in light of the recent case-law of the European Union Courts, ECEAE has failed to establish an interest in the result of the case.

12. Recently, the Court of Justice of the European Union has found that an interest to intervene can only be based on the impact of the decision on the legal situation of the association itself or of its members (Order of the Vice-President of the Court of Justice of 28 May 2018, *BASF Grenzach GmbH* v *ECHA*, C-565/17 P(R), EU:C:2018:340, and Order of 12 December 2017, *BASF Grenzach GmbH* v *ECHA*, T-125/17, EU:T:2017:931). The Agency argues that based on that case-law, the fact that ECEAE acts to protect the interests of animals is not sufficient on its own to show that its legal interests, or those of its members, would be affected by the Contested Decision.

13. The Agency argues that, based on the case-law referred to in the previous paragraph, ECEAE cannot qualify as a representative association that protects the interests of its members in the same way as a professional association. Therefore, the application to intervene should be considered under the case-law relevant to environmental non-governmental organisations ('NGOs').

14. The Agency argues that, in accordance with the Order of the General Court in *BASF Grenzach GmbH* v *ECHA*, T-125/17, ECEAE should, in order to demonstrate its interest to intervene in the case as an NGO, have established the existence of reports, programmes or studies showing a particular concern regarding the Substance. In this case, ECEAE failed to do so. Therefore, in the absence of evidence of a specific activity linked to the Substance, it cannot be held that ECEAE has an interest in the result of the present case.

15. In addition, ECEAE has not shown that it played any role in the decision-making process which lead to the adoption of the Contested Decision.

Reasons

16. Since the application to intervene complies with Article 8(2), (3) and (4) of the Rules of Procedure, the Board of Appeal will examine whether the application complies with Article 8(1) of the Rules of Procedure, in other words whether the Applicant has established an interest in the result of the present case.

17. Whilst the Board of Appeal uses the case-law of the Court of Justice of the European Union as guidance when applying Article 8(1) of the Rules of Procedure, the administrative nature of proceedings before the Board of Appeal must be borne in mind. The difference between proceedings before the Court of Justice of the European Union and the administrative proceedings before the Board of Appeal was highlighted by the General Court in the Order of 12 December 2017, *BASF Grenzach GmbH* v *ECHA*, T-125/17, rejecting an application to intervene by another animal welfare association, PETA International Science Consortium (PISC).

18. In addition, an implementing regulation such as the Rules of Procedure must be given, where possible, an interpretation consistent with the provisions of the basic regulation (see Case A-013-2016, *BASF Personal Care and Nutrition,* Decision of the Board of Appeal of 3 May 2017 on the application to intervene by ECEAE, paragraph 26). Article 8(1) of the Rules of Procedure should therefore be interpreted consistently with the REACH Regulation and the administrative nature of the appeals process.

19. The REACH Regulation foresees the involvement of stakeholders in the Agency's work through consultations and in the work of the committees established within the Agency (see, for instance, the fifth subparagraph of Article 85(4) and the fourth subparagraph of Article 86(1) of the REACH Regulation; see also Article 108 of the REACH Regulation in conjunction with the document endorsed by the Management Board of the Agency on 16 December 2011 on the Agency's approach to engagement with its Accredited Stakeholder Organisations, MB/69/2011 final). Such stakeholder involvement aims to ensure that different interests, including non-economic interests, are considered as part of the Agency's decision-making (see Case A-013-2016, *BASF Personal Care and Nutrition,* Decision of the Board of Appeal of 3 May 2017 on the application to intervene by ECEAE, paragraph 28). Furthermore, stakeholder involvement in the appeals process is consistent with the approach taken by the Agency and its Management Board, as explained above, especially in light of the fact that a decision of the Board of Appeal is the final step in the Agency's decision-making.

20. ECEAE is an Accredited Stakeholder Organisation with the Agency. As such, ECEAE must, by implication, fulfil the five eligibility criteria set out in the Revised Eligibility Criteria for ECHA's Accredited Stakeholders, adopted by the Management Board on 21 June 2011 (MB/34/2011; the 'Revised Eligibility Criteria'). The five criteria that an organisation must satisfy to become an Accredited Stakeholder Organisation are as follows:

    (i) They are legally established within the EU/EEA and have activities at the EU level;
    (ii) They have a legitimate interest in the areas of work of the Agency;
    (iii) They are representative in the field of their competence;
    (iv) They are non-profit making and do not exclusively represent individual companies; and
    (v) They are registered in the Register of Interest Representatives maintained by the European Commission. This last criterion only applies if they wish to participate as observers in the Committee and Forum meetings of the Agency.

21. Furthermore, with regards to the legitimate interest of an organisation in the work of the Agency, the Revised Eligibility Criteria sets out the following supporting definition:

    '*The organisation represents a sector affected by the EU chemicals legislation (such as the REACH, CLP, Biocides or PIC Regulation) falling within the scope of the tasks of ECHA. An organisation is also considered to have a legitimate interest in the areas of work of ECHA if it represents a sector indirectly affected by the legislation. This also includes [NGOs] engaged in issues affected by the mentioned legislation.*

    ECHA's Accredited Stakeholders are accordingly typically active in industry, human health, animal welfare, environmental protection, scientific research and development, and consumer protection.'

22. With regards to whether an organisation is representative in the field of its competence, the Revised Eligibility Criteria sets out the following supporting definition:

    '*The organisation must represent the interests of a substantial part of the actors in its field of competence. ECHA's Accredited Stakeholders should be representative of actors in their sector or field of competence. The necessary number of member organisations and their size depends on the structure of the relevant sector. Also, the sector need not have a particular size, but must be distinguishable from other sectors with different fields of interest*.'

23. Having regard to its status as an Accredited Stakeholder Organisation, the Board of Appeal finds that ECEAE has clearly established an interest in the field of the REACH Regulation and the work of the Agency in general. Furthermore, ECEAE is representative in the field of its competence.

24. An Accredited Stakeholder Organisation has an interest in the result of a case for the purposes of Article 8(1) of the Rules of Procedure if the case in question raises questions of principle capable of affecting its interests. The Board of Appeal will therefore next examine whether the present case raises questions of principle capable of affecting ECEAE's interests with regard to the avoidance of testing on vertebrate animals.

25. The REACH Regulation, for example in Article 1(1), seeks to promote and ensure various interests, including a high level of protection of human health and the environment, and the promotion of alternative methods for the assessment of the hazards of substances. In that regard, one of the objectives of the REACH Regulation is the promotion of non-animal testing and the replacement, reduction or refinement of animal testing required under it (see, for example, Article 138(9) of the REACH Regulation). In addition, *'stakeholders should continue to contribute to the promotion of alternative test methods [...] including computer supported methodologies*', and '*participation of stakeholders and initiatives involving all interested parties should be sought*' (see Recital 40 to the REACH Regulation).

26. In the present case the Appellant seeks the annulment of the Agency's decision requesting information on three studies requiring testing on vertebrate animals (see paragraph 2 above). The Appellant claims amongst other things that the Agency did not consider the

dossier update submitted by the Appellant prior to adoption of the Contested Decision which could have meant that the animal testing required in the Contested Decision is not necessary.

27. The present case therefore gives rise to questions of principle concerning the way the Agency reaches its decisions requiring tests on vertebrate animals. These questions concern the use of the cut-off point for dossier updates to be taken into consideration in the decision-making and the implications this has for the application of Article 25(1) of the REACH Regulation. These questions of principle have consequences beyond the circumstances of the present case in relation to dossier evaluation and testing on vertebrate animals. The appeal therefore raises questions of principle which relate directly to the avoidance of testing on vertebrate animals.

28. ECEAE, as an Accredited Stakeholder Organisation in a case which raises questions of principle regarding testing on vertebrate animals, therefore has an interest in the result of this appeal within the meaning of the first subparagraph of Article 8(1) of the Rules of Procedure.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Admits the application to intervene by ECEAE in Case A-001-2018 in support of the Appellant.**
2. **Instructs the Registrar to arrange for copies of the non-confidential versions of the Notice of Appeal and the Defence to be served on the Intervener.**
3. **Allows the Intervener a period of one month, following the serving of the Notice of Appeal and the Defence, to lodge a statement in intervention.**

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal